FEB - 5 2001

Attachment 5

510(k) Summary
Safety and Effectiveness

K003597

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Telephone Number: **Facsimile Number:**	(310) 645-8200 (310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Device Name **Trade:**	IMMULITE® Homocysteine IMMULITE® 2000 Homocysteine
Catalog Numbers:	LKHO1 (100 tests) L2KHO2 (200 tests)
Common: plasma or serum.	Reagent system for the determination of homocysteine in
Classification:	Class II device, LPS (21 CFR 862.1377)
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Establishment Registration Number:	DPC's Registration Number is 2017183
Substantially Equivalent Predicate Devices:	Abbott Diagnostics IMx
Description of Devices:	IMMULITE® Homocysteine is a clinical device for use with the IMMULITE® Automated Immunoassay Analyzer. IMMULITE® 2000 Homocysteine is a clinical device for use with the IMMULITE® 2000 Automated Immunoassay Analyzer.

Intended Use of the Devices:

IMMULITE and IMMULITE 2000 Homocysteine are for in vitro diagnostic use with their respective IMMULITE and IMMULITE 2000 Analyzers – for the quantitative measurement of L-homocysteine in human plasma or serum. These devices can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia or homocysteinuria.

Technology Comparison:

IMMULITE Homocysteine involves a preliminary manual sample pretreatment step. Homocysteine in the patient plasma or serum sample is released from its binding proteins and converted to S-adenosyl-homocysteine (SAH) by an off-line 30-minute incubation at 37°C in the presence of S-adenosyl-L-homocysteine hydrolase and dithiothreitol (DTT).

The treated sample and alkaline phosphatase-labeled anti-SAH antibody are simultaneously introduced into a test unit containing an SAH-coated polystyrene bead. During a 30-minute incubation, the converted SAH from the patient sample competes with the immobilized SAH for binding the alkaline phosphatase labeled-anti-SAH antibody conjugate. Unbound enzyme conjugate is removed by centrifugal wash. Substrate is added, and the Test Unit is incubated for a further 10 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex - and thus also the photon output, as measured by the luminometer - determines the concentration of homocysteine in the sample.

IMMULITE 2000 Homocysteine involves performing an on-line one-cycle sample pretreatment of patient plasma or serum with S-adenosyl-L-homocysteine (SAH) hydrolase and dithiothreitol (DTT) solution in a reaction tube containing no bead. After a 30-minute incubation, the treated sample is transferred to a second reaction tube containing a SAH-coated polystyrene bead and an alkaline phosphatase-labeled antibody specific for SAH. During a 30-minute incubation, the converted SAH from the sample pretreatment competes with immobilized SAH for binding alkaline phosphatase-labeled anti-SAH antibody. Unbound enzyme conjugate is removed by centrifugal wash. Substrate is added and the reaction tube is incubated for a further 10 minutes.

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Abbott IMx Homocysteine utilizes fluorescence polarization immunoassay technology. The probe/electrode assembly delivers the sample, Pretreatment Solution, Enzyme, and FPIA#1 Diluent Buffer to the predilution well of the sample cartridge.

The Pretreatment Solution (dithiothreitol) reduces homocysteine and mixed disulfide and protein-bound forms of homocysteine in the sample to form free homocysteine. S-adenosyl-L-homocysteine Hydrolase convert total free homocysteine to S-adenosyl-L-homocysteine (SAH)

An aliquot of the predilution mixture, Antibody, and FPIA#1 Diluent Buffer are delivered to the cuvette and a background measurement is made by the FPIA optical assembly. Tracer, FPIA#1 Diluent Buffer, and a second aliquot of the predilution mixture are transferred to the cuvette. SAH and the labeled Fluorescein Tracer compete for the sites on the monoclonal antibody molecule. The intensity of polarized fluorescent light is measured by the FPIA optical assembly.

Method Comparison:

The IMMULITE 2000 procedure was compared to Abbott Diagnostics IMx on 113 plasma samples, with homocysteine concentrations ranging from approximately 4 to 23 µmol/L. Linear regression analysis yielded the following statistics:

(IML2000) = 0.90 (IMx) - 0.02 µmol/L r = 0.925

Means: 8.7 µmol/L (IML2000)
9.6 µmol/L (IMx)

The IMMULITE procedure was compared to IMMULITE 2000 on 110 plasma samples, with homocysteine concentrations ranging from approximately 4 to 39 µmol/L. Linear regression analysis yielded the following statistics:

(IMMULITE) = 1.05 (IML2000) + 0.25 µmol/L r = 0.980

Means: 12.5 µmol/L (IMMULITE)
11.7 µmol/L (IML2000)

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for IMMULITE® Homocysteine and IMMULITE® 2000 Homocysteine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2001

Dr. Edward M. Levine
Director, Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597

Re: K003597
Trade Name: IMMULITE® Homocysteine and IMMULITE® 2000 Homocysteine
Regulatory Class: II
Product Code: LPS
Regulatory Class: I reserved
Product Code: JJX
Dated: January 25, 2001
Received: January 26, 2001

Dear Dr. Levine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 3

510(k) Number (if known): K003597
Device Name: IMMULITE® Homocysteine and IMMULITE® 2000 Homocysteine

Indications For Use:

IMMULITE and IMMULITE 2000 Homocysteine are for *in vitro* diagnostic use with their respective IMMULITE and IMMULITE 2000 Analyzers – for the quantitative determination of L-homocysteine in human plasma or serum. These devices can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia or homocysteinuria.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) for Joan Cooper
Division of Clinical Laboratory Devices
510(k) Number K003597

✓ Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)